IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Norihiro NISHIMOTO et al.

Title: TREATMENT OF VASCULITIS WITH IL-6 ANTAGONIST

(AS AMENDED)

Appl. No.: 10/596,429

International 12/17/2004

Filing Date:

371(c) Date: 08/07/06

Examiner: Lorraine Spector

Art Unit: 1647

Confirmation 6508

Number:

DECLARATION

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

I, Simon J. Elliott, declare:

Deposits under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure have been made as follows:

- 1. The cell line which produces PM-1 antibody, deposited on July 12, 1989, with the Fermentation Research Institute, Agency of Industrial Science and Technology, 1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305 Japan, and accorded Accession No. FERM BP-2998. (The cell line was originally deposited on July 12, 1989, accorded Accession No. FERM P-10839, and was then transferred to Accession No. FERM BP-2998 on July 10, 1990.)
- 2. The hybridoma cell line which produces MR16-1 antibody, deposited on March 13, 1997, with the National Institute of Bioscience and Human Technology, Agency of Industrial Science and Technology, 1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305 Japan, and accorded Accession No. FERM BP-5875.

Atty. Dkt. No. 053466-0417

3. The name and address of the depository institute has been changed to "the National

Institute of Advanced Industrial Science and Technology, Patent and Bio-Resource Center,

Chuo-6, 1-1, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305-5466, Japan."

4. Copies of the receipts of original deposits, and English translations, of the above-

identified international deposits are provided herewith.

5. The deposit shall be made for a term of at least thirty (30) years, and at least five (5)

years after the most recent request for the furnishing of a sample of the deposit was received

by the depository. Samples will be stored under agreements that would make them available

beyond the enforceable life of the patent for which the deposit was made. 37 C.F.R. § 1.806.

6. All restrictions on the availability to the public of the cultures deposited will be

irrevocably removed upon the granting of a patent from the above-identified application.

37 C.F.R. § 1.808.

7. I hereby declare that all statements made herein of my own knowledge are true and

that all statements made on information and belief are believed to be true; and further that

these statements were made with the knowledge that willful false statements and the like so

made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such

willful false statements may jeopardize the validity of the application or any patent issued

therefrom.

Respectfully submitted,

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Simon J. Elliott

Attorney for Applicants

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DEPOSITOR
Name Tadamitsu Kishimoto

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

Address 5-31, Nakano-cho 3-chome, Tondabayashi-shi, Osaka 584

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Rule 7.1 by the

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the DEPOSITOR: PM1

(Deposition Number)

FERM BP-2998

II. SCIENTIFIC DESCRIPTION AND/OR TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

a scientific description

x a proposed taxonomic designation

(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above, which was received by it on July 12, 1989 (Date of the original deposit)¹.

(Transferred from FERM P-10839 deposited on July 12, 1989.)

IV. INTERNATIONAL DEPOSITARY AUTHORITY

Fermentation Research Institute

Agency of Industrial Science and Technology

Director General Tomoo Suzuki

1-3, Higashi 1 chome, Tsukuba-shi, Ibaraki-ken, 305, Japan

July 10, 1990

、 特許手法上の数些物の寄托の田線的承辺) に関するブダベスト条約

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

BUDAPEST TREATY ON THE INTERNATION NAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF

下記回際名託当局によって規則7.1に従い 発行される

原寄託についての受託証

issued pursuant to Rule 1.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

黔

氏名 (名称)

岸本 忠三・・

PATENT PROCEDURE

SF

あて名 🕏 584

大阪府富田林市中野町 3丁目 5 春 3 1号

1. 単生物の表示 (寄託者が付した試別のための表示) (受託委号) **对工研究等第** PW1 2998 (FERM BP- 2998) . 1. 科学的装賞及び分類学上の位置 十二の関生物には、次の手項を記載した文書が活付されていた。 . 📗 科学的世界 区 分類学上の位置 11. 受領及び受託・ 本民際寄託当局は、平成 元年 7月12日(原寄託日)に受領した「福の敵生物を受託する。 7万12亩に寄託された炭工研萄寄第 P- 10839 俘或 元年 号より移変) N. 田松花託当局 通商覆菜省工菜技術院改生物工菜技術研究所 名 祢: 给 木 智 . DIRECTOR CENERAL. Tomoo あて名: 日本 白 茨 報 県 つ (紅 市 耳) 丁 目) 祭 3 号 (菊 便 寄 号 3 0 5) 1-3. Higashi I chome Tsukuba-shi Ibaraki-ken JOS. JAPAN 平成 2年 (1990) 7月 10日

- 国際様式

特許手続上の微生物の寄託の国際的承認 に関するブタベスト条約

下記国際寄託当局によって規則7. 1に従い 発行される。

原寄託についての受託証

BUDAPEST TREATY ON THE INTERNATIO-NAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

氏名(名称)

中外製薬株式会社

取締役社長 永山 治

森託者

〒 115 あて名

東京都北区浮間5丁目5番1号

殿

1. 微生物の表示

(寄託者が付した識別のための表示)

Rat-mouse bybridoma MR16-1

(受託番号) FERM BP- 5875

2. 科学的性質及び分類学上の位置

1 棚の微生物には、次の夢項を記載した文書が添付されていた。

- 科学的性質
- 分類学上の位置

3. 受領及び受託

本国際寄託当局は、 平成 9 年 3 月 1 3 日(原寄託日)に受領した1 棚の微生物を受託する。

4. 移管請求の受領

本国際寄託当局は、

月 日 (原寄託日) に1 桐の敬生物を受領した。

そして、

月 日 に原寄託よりブダベスト条約に基づく寄託への移管請求を受領した。

5. 国際寄託当局

通商産業省工業技術院生命工学工業技術研究所

National Institute of Bioscience and Human-Technology Agen (五字) Agen

あて名: 日本 国 茨 坂に原って近いでは、市 京 1 丁 目 1 番 3 号 (의便番号305)

305. JAPAN

平成 9年 (1997) 3月13日

Depositor

Name: CHUGAI SEIYAKU

KABUSHIKI KAISHA

Representative: Osamu Nagayama

Address: 5-1, Ukima 5-chome,

Kita-ku, Tokyo 115

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL

DEPOSIT

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this

page.

IDENTIFICATION OF THE MICROORGANISM 1.

Identification reference given by the DEPOSITOR: Rat-mouse hybridoma MR16-1 (Deposition Number)

FERM BP-5875

SCIENTIFIC DESCRIPTION AND/OR TAXONOMIC DESIGNATION 2.

The microorganism identified under 1 above was accompanied by:

- a scientific description
- a proposed taxonomic designation

(Mark with a cross where applicable)

RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under 1 above, which was received by it on March 13, 1997 (Date of the original deposit)1.

RECEIPT OF TRANSFER 4.

> This International Depositary Authority accepted microorganism (Date of the identified under 1 above, on original deposit), and accepted a request for transfer to a deposition under Budapest treaty from the original deposition, , (Transferred from FERM P on OD

INTERNATIONAL DEPOSITARY AUTHORITY 5.

National Institute of Bioscience and Human-Technology

Agency of Industrial Science and Technology

Director General Michio Oishi

1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305, Japan

March 13, 1997